

JUN 05 2013

HEARTSTRING III Proximal Seal System

510(k) Summary

Prepared in accordance with 21 CFR Part 807.92

510(k) Number: K130382

Date Prepared: 6 March 2013

Device Owner: MAQUET Cardiovascular LLC
45 Barbour Pond Drive
Wayne, New Jersey 07470

Contact Personnel: Mark Dinger
Title: Regulatory Affairs Specialist II
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Phone: 973-709-7691 **Fax:** 973-807-1658

Trade Name: HEARTSTRING III Proximal Seal System

Device Generic Name: Vascular Clamp

Classification: According to 21 CFR 870.4450 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Product code DXC.

Predicate Device: K080169 HEARTSTRING III Proximal Seal System (SE: 8 Feb 2008)

Device Description: The HEARTSTRING III Proximal Seal System is a device designed to enable the creation of a proximal anastomosis of a vessel graft to the aorta without the need for an aortic clamp during coronary artery bypass graft (CABG) surgery.

The HEARTSTRING III Proximal Seal System is comprised of the Proximal Seal, Delivery Device, Loading device and Aortic Cutter. The HEARTSTRING III Seal is a device that is delivered into the aorta via an aortotomy created by the Aortic Cutter and provides a sealed region to facilitate the proximal anastomosis. The Delivery Device is a syringe-like tube with plunger that is used to deploy the HEARTSTRING III Seal inside of the aorta. The Loading

Device is a mechanism that rolls the HEARTSTRING III Seal and loads the HEARTSTRING III Seal into the Delivery Device. The Aortic Cutter is a single use (one aortotomy) device that consists of a Grip, a Cutter, Aortic Stop, a Cap, a Needle, a Safety Lock and an Actuation Button. It is used to create the aortotomy for the anastomosis.

Indications for Use:

The HEARTSTRING III Proximal Seal System is intended for use by Physicians during CABG procedures to maintain hemostasis and to facilitate the completion of a proximal anastomosis to the aorta without application of an aortic clamp.

Technological Characteristics

The Proposed HEARTSTRING III Proximal Seal System and the predicate devices have the following similarities:

- the same but clarified intended use,
- the same operating principles,
- incorporates the same seal device,
- sterilized using the same materials and processes,
- has same packaging.

The Proposed HEARTSTRING III Proximal Seal System and the predicate devices have the following differences:

- Addition of a bridge on the loading device.
- Addition of visual cues on the loading and delivery device.
- Change branding colors on loading and delivery device.

This difference is not considered a technological difference and is substantially equivalent to the predicate devices.

Safety and Performance:

MAQUET Cardiovascular's development process required that the following activities be completed during the development of the Proposed HEARTSTRING III Proximal Seal System:

- Performance testing
- Biocompatibility Testing

The results of the in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed HEARTSTRING III Proximal Seal System.

Conclusion:

Based upon the information submitted in this Traditional 510(k) premarket notification, MAQUET's HEARTSTRING III Proximal Seal System is substantially equivalent to the currently marketed HEARTSTRING III Proximal Seal System. The HEARTSTRING III Proximal Seal System is similar to the predicate devices in the intended use and the fundamental scientific technology of the device. The performance testing established that the proposed HEARTSTRING III Proximal Seal System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 5, 2013

Maquet Cardiovascular LLC
c/o Mr. Mark Dinger
Regulatory Affairs Specialist, II
45 Barbour Pond Drive
Wayne, NJ 07470

Re: K130382
Trade/Device Name: Heartstring III Proximal Seal System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: March 6, 2013
Received: March 7, 2013

Dear Mr. Dinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Mark Dinger

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130382

Device Name: HEARTSTRING III Proximal Seal System

Indications For Use:

The HEARTSTRING III Proximal Seal System is intended for use by Physicians during CABG procedures to maintain hemostasis and to facilitate the completion of a proximal anastomosis to the aorta without application of an aortic clamp.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of

Matthew G. Hillebrenner